

REMARKS/ARGUMENTS

Claims 1-10 and 21-22 are canceled.

Upon entry of the amendment, Claims 11-20 will be active.

No new matter is believed to have been added.

The objection to Abstract is believed to be obviated by the cancellation of all previous versions of the Abstract, and the submission, along with this paper, of a substitute Abstract.

The obviousness rejection of Claims 11-20 as being unpatentable over Yanagawa in combination with the 1994-1995 Drug Information Handbook (DIH) is respectfully traversed,

At the outset, Applicants note that Yanagawa, at column 3, lines 6-41, for example, describes over 50 possible carriers. Yanagawa does not describe or suggest that carriers found in Claim 11, for example, calcium carbonate and calcium phosphate and combinations thereof, are particularly suitable as carriers in a composition for nasal administration.

Further, Yanagawa does not describe or suggest that compositions comprising the carriers found in Claim 11, for example, calcium carbonate, calcium phosphate and combinations thereof, having an average particle size of 20 to 100  $\mu\text{m}$ , and an effective dose of an opioid analgesic uniformly distributed on the carrier, produce remarkable nasal absorption effects.

For example, page 6, lines 12-20 of the specification, describe superior and unexpected results of the presently claimed composition embodiments – that, when compared to oral administration of an opioid analgesic - intranasal administration of the presently claimed composition embodiments results in higher opioid analgesic absorption and a steeper rise in the opioid analgesic absorption curve.

Moreover, Applicants submit that the presently claimed composition embodiments, as when administered intranasally, have prolonged analgesic effects when compared with conventional routes of opioid analgesic administration (e.g., intrarectal and intravenous

Application No. 10/519,677  
Reply to Office Action of February 6, 2007

administration), and result higher opioid analgesic plasma concentrations (see, for example, Tables 7 and 8, page 24 of the specification, for plasma concentrations of fentanyl at the 240 minute mark).

Finally, as described at page 25 of the specification, the claimed composition embodiments bring great improvement to cancer pain control. Withdrawal of the obviousness rejection is requested.

The double patenting rejection of Claims 11-20 over Claims 1-2, 4 and 9-14 of Yanagawa in combination with the DIH is respectfully traversed, because the cited claims do not describe or suggest all of the limitations of the present claims. Withdrawal of the double patenting rejection is respectfully requested.

Applicants submit the application is now in condition for allowance, and kindly request the claims be passed to issue. Early notification to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

  
Charles J. Andres Jr., Ph.D.  
Attorney of Record  
Registration No. 57,537

Customer Number  
**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 06/04)